UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,670	10/31/2003	Ruth E. Leibig	2003P12088US	3568

7590 11/19/2004	**EXAMINER**
Siemens Corporation	JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
3737	

Siemens Corporation
Attn: Elsa Keller, Legal Administrator
Intellectual Property Department
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DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/698,670	LEIBIG ET AL.
	Examiner	Art Unit	
	Jaworski Francis J.	3737	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>5-7-2004(IDS)</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1 - 45</u> is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-15 and 17-45</u> is/are rejected.

7)☒ Claim(s) <u>16</u> is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>31 October 2003</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All   b)☐ Some * c)☐ None of:

   1.☐ Certified copies of the priority documents have been received.

   2.☐ Certified copies of the priority documents have been received in Application No. _____.

   3.☐ Copies of the certified copies of the priority documents have been received in this National Stage

      application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date <u>05072004</u>.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Specification

The Examiner considered this case for species election since the specification noted that 1) options for the data being acted on for automatic marking or storing included local memory, external storage or a workstation archive source or a network source such as data from another imager, and 2) options for distinguishing events included ECG abnormalities, transducer motion state, cessation of fetus motion, contrast agent brightness or high velocity Doppler states. However in applying the test that the options were non-trivially patentably distinct (prior to actual search) and also mutually alternative under the disclosure, the latter criterion is unmet in both cases, since in the case of memory site and type options the specification notes in para [0050] that activity controls for marking and storage as represented by the Fig. blocks (the storage being into 116, 124, 126 or 128) then such blocks may be merged so that a local recognition processor can mark images going into an archive in which the automatic selective storage is completed and so forth, and in the case of distinguishing event option scenarios these study types may occur together in a single study as spelled out in para [0036].

The full line appearing below claim 44 on page 28 should be deleted since it confuses the fact that a final claim45 is present thereafter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[Parenthesized claim number(s) represent the claim or claims being

addressed by the immediately preceding rejection.]

Claims 1 - 3, 9, 20, 29, 44 are rejected under 35 U.S.C. 102(b) as being

anticipated by Roth (US5315512).

Roth teaches an ultrasound diagnostic system and method including

structure and steps for use of:

an event recognition processor 110 within processing subsystem 100

which processor operates to

a. recognize an event (ECG trigger and under optional interpretation a

respiratory extremum and under further optional interpretation the selecting i.e.

not discarding only those of the ECG and/or respiratory gates associated with

non-anomalous intervals, see 650 of Fig. 6 and 755 of Fig. 7) via the respective

physiologic monitors shown in Fig. 1 soas to constitute a subset of an ultrasound

examination, and

b. select a portion of the ultrasound examination to be marked as well as

stored (col. 9 lines 14 – 16 pertain to this selective retention for further

processing) by performing:

i. automatic time marking of the events using time-of-day marking (col. 6

lines 34 – 43),

ii. effectively a causing of the events to be so-marked,

iii. automatically storing the one or more events (see step 431 of Fig. 4)

and therefore

iv. automatically causing the events to be stored

v. automatically terminating storage of a portion of the ultrasound exam

(in Roth et al the storage selectivity is practiced on an image frame cluster about

the trigger time, see col. 7 lines 31 – 36. The actual terminating of storage is

then decision output NO of protocol step 875 in Fig. 8B ending digitization and

storage 865, 866 and 870) and therefore

vi. automatically causing termination of storage of a portion of the

ultrasound exam. (Claim 1).

Since Roth operates retrospectively, all data sets are captured and reviewed for distinguishing events and selection and marking for digitization and frther storage. (Claim 29).

Since in Roth an interrupt to the processor 110 is manually provided by the operator if the probe position status is unsuitable for any reason, see col. 6 lines 26 – 29, such a structure *is capable of manual triggering if a stationary probe position is not maintained*, and would provide an inhibitory override to frame selection. Since claim 2 does not indicate in its wording that the event recognition of the base claim is referenced ('said distinguished event' for example) then the above interpretation is anticipatory against the language as stated. (Claim 2).

Element 755 of Fig. 7 effectively recognizes an ECG irregularity such as an extra-systole as 'a distinguished event' (not a 'said automatically distinguished event', see claim 2 reasoning) which impacts selection. (Claim 3).

Since the selection in Roth occurs subsequent to the time marking the frames which are captured are set to cluster about the trigger point, see col. 7 lines 30 – 37 hence late diastole/atrial systole phase might constitute the first portion of the exam and ventricular contraction after the R-wave trigger indicating onset of contraction would constitute the second portion. (Claim 9).

Roth et al further notes that either direct or retrospective digitization governed by the selectivity may be practiced dependent on how static or rapidly changing the region being evaluated is, see col. 6 lines 30 – 36. (Claims 20, 44).

[Note: these selectivity/marking processes are 'manual' to the extent that the operator ultimately dictates the rejection/retention criteria with respect to anomalous physiologic cycles as well as the frame clustering within an ideal retention cycle, see col. 7 lines 23 – 30 and col. 11 lines 2 – 12. However these are a 'priming' or initializing of the system after which the digitized image acquisition including associated markings and acquisitions proceeds 'automatically' without further user prompts.]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 33 – 35 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Roth as argued against claims 1, 29 further in view of Mo et al (US6012458)...

Roth as noted is directed to automatic marking and selection of image frames for digitization and display retention. Roth et al does not explicitly teach the recognition of a substantially stationary probe as a ('said automatically selected') distinguishing event under narrow interpretation since in Roth only certain probe position artifact circumstances are identified and then only manually acted upon by the operator, again see col. 6 lines 26 – 29, However it

would have been obvious in view of Mo et al col. 6 lines 4 – 19 to automatically

inhibit frame retention in Roth based upon a non-stationarity threshold between

images, meaning retain frames only associated with a substantially stationary

probe and/or slow probe advance since Mo et al is similarly directed to volumetric

scanning (col. 2 lines 26 – 33) and to an untethered or freehand scan (col. 3 lines

8 – 28) analogous to the spatial locator system centered on element 150 of Roth.

(Claims 2, 33 - 35).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Roth as applied to claim1 above, and further in view of Hoff et al (US6315730).

Whereas Roth is silent as to relationship with contrast brightness change, it

would have been obvious in view of Hoff et al col. 7 lines 12 – 24 to associate the

ECG triggering with the onset of wash-in of contrast agent and therefore with

contrast brightness change as a distinguishing event since this can serve to

identify regions of hypo-perfused cardiac tissue. (Claim 4).

Claims 5 – 8, 10 – 11, 21- 28, 30, 36, 38 - 43 and 45 are rejected under 35

U.S.C. 103(a) as being unpatentable over Roth as applied to claims 1, 20 or 29

above, and further in view of Ramamurthy et al (US5846202). Roth per se is

silent as to the use of Doppler events including color Doppler jetting as a

distinguishing event either as a broad interpretation of claim language (meaning

not necessarily governed by the antecedent terminology, i.e. 'said automatically

marked or selected event' not implied.) or as a narrow interpretation, since

Doppler mode is never addressed. However it would have been obvious in view

of Ramamurthy et al col. 13 lines 45 – 67 to use various imaging modalities

including Doppler with pulse Doppler as a trigger, including a jetting or highest velocity of color Doppler as a trigger in substitution for the ECG trigger in Roth since Ramamurthy et al elsewhere note (col. 9 lines 3 – 20 and col. 11 lines 48 – 50) that highest value Doppler indicative of high mean flow would be useful in measuring arterial perfusion, e.g. in a coronary artery. (Claims 5, 36, 39)..

In Roth et al as modified by Ramamurthy et al Fig. 4D, the event recognition processor would act to recognize a pair of events 72(2), 74(2) which brackets the portion (2) of the ultrasound examination of interest, and selects or activates for color Doppler display the temporal portion of frames which occurs in between this pair of events. In the alternative, Ramamurthy et al directly proposes that plural triggers associated with differing distinguishing events may be used, see col. 8 lines 29 – 39. (Claims 6, 38, 40).

Such an action in Roth if practiced retrospectively from initial storage would necessarily be associated with markers identifying the begin-trigger and end-trigger points. (Claim 7).

Insofar as the sequence repeats as 72(3), 74(3) then each subset 72(N), 74(N) is marked or captured by the recognition processor along with additional portions of the exam 72(N-1), 74(N-1) prior to the exam and after the exam, 72(N+1), 74(N+1). (Claims 8, 21 – 22, 26, 30, 41).

Since the B-mode imaging continues throughout, it is characterizable as a preview or post-view subset of frames during the selection intervals where color Doppler is not being produced and whose intervals are identifiable by the markers which identify the Doppler storage intervals. (Claims 27 – 28, 42 - 43).

Whereas Roth is further silent as to select amongst retention states based upon characterization of a feature, it would have been obvious in view of Ramamurthy et al e.g. col. 9 lines 3 – 18 and col. 13 lines 57 – 60 to select a final retention state of highest Doppler mean velocity or energy or variance based upon mathematical characterization of this parameter within each image frame, and to cause display of the final frame stored for this feature characterization of e.g. coronary blood pool motion. (Claims 10, 11, 23 – 25, 39, 45).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roth in view of Ramamurthy et al as applied to claim10 above, and further in view of Hoff et al since whereas the former is silent as to brightness change as a characterizing feature the latter indicates that triggering can be adapted based upon the ECG trigger gating such as taught in Roth to act on a change in brightness soas to track wash-in of a contrast agent for purposes of perfusion study. (Claim 12).

Claims 13, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth as applied to claims 1 or 29 above, and further in view of Ramamurthy et al as the latter was applied above, further in view of Holupka (UD5810007). Whereas the former are silent as to image cropping, it would have been obvious in view of the latter col. 6 lines 19 – 27 to crop the image produced by Roth as modified for Doppler mode by Ramamurthy et al since Holupka et al note that it was conventional to automatically crop an image to exclude data not associated with the particular imaging modality hence for Doppler flow data the echo data

from static anatomy in the periphery of the image frame would be such a category of data which is unnecessary for a flow mode study. (Claims 13, 32).

Claims 14 – 15 and 17 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth as applied to claim 1 above, and further in view of Greer et al (US5959622). The former is silent as to indicators of image selection capture. However it would have been obvious in view of the latter to provide audible or visible indication of capture, the latter in a way that is suitable for display to represent progression on a graphical user interface such as a symbol or increment of a number.when triggering capture is prior-ordered to occur automatically since there would otherwise be no immediate prompt to the user that the previously ordered event capture had by now occurred. (Claims 14 – 15, 17 – 19).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al in view of Ramamurthy et al as applied to claim 30 above, and further in view of Hossack et al (US6042545). Whereas the former are silent as to use of decimation, it would have been obvious in view of Hossack et al col. 7 lines 56 – 66 to practice decimation of data in association with a selection system as per col. 2 lines 50 – 65 since this facilitates the application of preliminary filtering and applied gain for example. (Claim 31).

Claims 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roth in view of Ramamurthy et al as applied to claim 36 above, and further in view of Hoff et al which as noted above in relation to deficiency of teaching in

Roth teaches determinations made in conjunction with change of brightness

when a contrast wash-in protocol is being used.. (Claim 37)

Allowable Subject Matter

Claim 16 is objected to as being dependent upon a rejected base claim,

but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Jaworski

Francis J. at telephone number 1 – 571 – 272 – 4738.

FJJ:fjj

11-09-2004

Primary Exr
AU 3737